NIST- Traceable Primary Standards (FC)

1. Purpose and Scope

Primary Standards are used to verify the retention time and molecular spectrum as well as validating the Library Search algorithm.

2. Definitions

GC/MS	Gas Chromatograph/Mass Spectrometer
NIST	National Institute of Standards and Technology Traceable Instrumentation
Standard	any material purchased having a known concentration to be used for controls in an analysis
Traceability	Ability to trace the history, application, or location of a product through identification at specified intervals.
Validation:	the process of experimentation and review which establish the efficacy and reliability of a new or modified technique or procedure.
Verification	Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

3. Safety Instructions

No safety instructions are identified for this instruction.

4. Instructions

1. **Procedure for Use of Primary Drug Standards.**
   Primary drug standards are purchased through

   Cerilliant Corporation (ISO 9001; 2000 registered)

   811 Paloma Drive, Suite A

   Round Rock, Texas, 78665

   Those standards desired but not available through Cerilliant may be ordered through another vendor.

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Instructions (Continued)

(ie. Sigma Aldrich, LipoMed, Supelco etc.)

Log date of receipt in Standards Logbook

File documentation (Analytical Data provided, NIST Traceability)

Run Standard on GC/MS for retention time and mass spectrum.

Store one copy with original vendor documentation.

Shelf life of primary standard 5 years, unless otherwise noted.

5. Notes

INTERPRETATIONS:

LIMITATIONS:

MISCELLANEOUS:

6. FC-Instruments/Equipment/Materials

No fc-instruments/equipment/materials are identified for this instruction.

7. FC-Chemicals/Reagents

No fc-chemicals/reagents are identified for this instruction.

8. Records

No records are created by this instruction.

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9. Policy References

Technical requirements	5
General	5.1
Test and calibration methods and method validation	5.4
Equipment	5.5
Measurement traceability	5.6
Sampling	5.7
Handling of test and calibration items	5.8
Assuring the quality of test and calibration results	5.9
Reporting the results	5.10

10. Procedure References

No procedures are referenced by this instruction.

11. Instruction References

No instructions are referenced by this instruction.

12. Other Reference Documents

There are no other reference documents for this instruction.